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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/666,146	09/20/00	RIETHMULLER-WINZEN	H	PM 268411

000909
PILLSBURY WINTHROP LLP
1600 TYSONS BOULEVARD
MCLEAN VA 22102

HM12/0718

EXAMINER	
HUI, S	
ART UNIT	**PAPER NUMBER**
1617	8

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/666,146	RIETHMULLER-WINZEN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of the invention of Group I, claims 1-13 in Paper No. 5, received June 5, 2001, is acknowledged. The traversal is on the ground(s) that the method of Group I can be concurrently searched with the compounds claimed without undue burden on the examiner. This is not found persuasive because the search field for a composition as claimed herein containing certain ingredients is different from and non-coextensive with the search field for a particular method of use employing the same composition. Note that the search is not limited to the patent files. Therefore, also the search for the compositions and methods claimed herein encompassed by the claims presents an undue burden to the Office.

The restriction requirement is still deemed proper and is therefore made FINAL.

On reconsideration, the examiner withdraws the species election requirement in the previous office action.

Claims 14-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claim Objections

Claim 1 is objected to because of the following informalities: the use of parenthesis in claim 1, line 2: "(FTO)", is considered improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for LHRH antagonists disclosed in page 5, line 20-24, does not reasonably provide enablement for other LHRH antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, there is no adequate direction provided by the applicant as to how to select other LHRH antagonists would be suitable to therapeutically manage extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Furthermore, the instant specification does not provide any working examples to point out how administration of other LHRH antagonists, other than the ones disclosed in page 5, line 20-24, may be used successfully in the claimed method of treating extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Moreover, it is known in the art that different active compounds that have structural differences may have different chemical and physical properties giving rise to differences in *in vivo* potency and activity. Therefore, LHRH antagonists, other than the one disclosed in page 5, line 20-24 would result in correspondingly different activity for the resulting compounds. Due to this unpredictability, it would prevent the skilled artisan from selecting a LHRH antagonist to retain the function of the instant extrauterine

proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction treating method without undue experimentation.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oral contraceptives disclosed in page 7, line 29 – page 8, line2, does not reasonably provide enablement for other contraceptives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, there is no adequate direction provided by the applicant as to how to select other contraceptives would be suitable to therapeutically manage extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Furthermore, the instant specification does not provide any working examples to point out how administration of contraceptives in combination of LHRH antagonist may be used successfully in the claimed method of treating extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Moreover, it is known in the art that different active compounds that have structural differences may have different chemical and physical properties giving rise to differences in *in vivo* potency and activity. Therefore, compounds that are used for contraception, for example, spermicide compounds for topical or intravaginal application, would result in correspondingly different activity for the resulting compounds. Due to this unpredictability, it would prevent the skilled artisan from

selecting a contraceptive to retain the function of the instant extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction treating method without undue experimentation.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non-steroidal anti-rheumatoid agents disclosed in page 8, line 16, does not reasonably provide enablement for other non-steroidal anti-rheumatic agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, there is no adequate direction provided by the applicant as to how to select other non-steroidal anti-rheumatic agents would be suitable to therapeutically manage extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Furthermore, the instant specification does not provide any working examples to point out how administration of non-steroidal anti-rheumatic agents in combination of LHRH antagonist may be used successfully in the claimed method of treating extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Moreover, it is known in the art that different active compounds that have structural differences may have different chemical and physical properties giving rise to differences in *in vivo* potency and activity. Therefore, a non-steroidal anti-rheumatic compounds, other than the one disclosed in page 8, line 16, for example, auranofin and

sulfasalazine, would result in correspondingly different activity for the resulting compounds. Due to this unpredictability, it would prevent the skilled artisan from selecting a non-steroidal anti-rheumatic agent to retain the function of the instant extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction treating method without undue experimentation.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for analgesic compounds disclosed in page 8, line 17-18, does not reasonably provide enablement for other analgesic compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, there is no adequate direction provided by the applicant as to how to select other analgesic compounds would be suitable to therapeutically manage extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Furthermore, the instant specification does not provide any working examples to point out how administration of analgesic compounds in combination of LHRH antagonist may be used successfully in the claimed method of treating extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Moreover, it is known in the art that different active compounds that have structural differences may have different chemical and physical properties giving rise to differences in *in vivo* potency and activity. Therefore, analgesic compounds, other than

the one disclosed in page 8, line 17-18 would result in correspondingly different activity for the resulting compounds. Due to this unpredictability, it would prevent the skilled artisan from selecting an analgesic compound to retain the function of the instant extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction treating method without undue experimentation.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for androgen compounds disclosed in page 8, line 4-8, does not reasonably provide enablement for other androgen compound agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, there is no adequate direction provided by the applicant as to how to select other androgen compounds would be suitable to therapeutically manage extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Furthermore, the instant specification does not provide any working examples to point out how administration of androgen compounds in combination of LHRH antagonist may be used successfully in the claimed method of treating extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction.

Moreover, it is known in the art that different active compounds that have structural differences may have different chemical and physical properties giving rise to differences in *in vivo* potency and activity. Therefore, androgen compounds, other than

the one disclosed in page 8, line 16 would result in correspondingly different activity for the resulting compounds. Due to this unpredictability, it would prevent the skilled artisan from selecting an androgen compound to retain the function of the instant extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction treating method without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 7, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation

"between about 35 pg/ml and about 80pg/ml" in line 2; the claim also recites "between about 45-75 pg/ml", and "between about 50 - 75 pg/ml" in line 3 which is the narrower statement of the range/limitation.

Claim 3 recites the broad recitation "a contraceptive" in line 2, and the claim also recites " an oral contraceptive" in line 3 which is the narrower statement of the range/limitation.

Claim 7 recites the broad recitation "a contraceptive" in line 3, and the claim also recites " an oral contraceptive" in line 4 which is the narrower statement of the range/limitation.

Claim 8 recites the broad recitation "early to mid follicular phase" in line 2, and the claim also recites " cycle day one to three" in line 2 which is the narrower statement of the range/limitation.

Claim 9 contains the trademark/trade name D-63153. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific LHRH antagonist and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al. (US Patent 5,663,145) in view of Hodgen (US Patent 5,658,884 from the Information Disclosure Statement received June 5, 2001) and Nachtigall et al. (Chapter 41, Danforth's Obstetrics and Gynecology, 1994, page 757-769).

Engel et al. teaches a method of administering the LHRH antagonist, cetrorelix, in two phases, to a patient in treatment of endometrial hyperplasia (See particular claim 14). Engel et al. also teaches that the dosage of cetrorelix useful in the method is 1 mg to 60 mg (See particular col. 3, line 8-9).

Engel et al. does not expressly teach the use of other agents in the method of treating endometrial hyperplasia. Engel et al. does not expressly teach the administration of the LHRH antagonist that cause the estrogen serum level to be 35-80 pg/ml, 45-75 pg/ml, or 50-75 pg/ml. Engel et al. does not expressly teach the time and the frequency of administration of Cetrorelix.

Hodgen teaches administration of GnRH antagonist in a method of treating endometriosis such that the estrogen level would be between 35 - 50 pg/ml (see particular col. 7, line 12-28; also col. 7, line 66 – col.8, line 4; also claims 9, 10, 12,13, 15, 16, 18, and 19).

Nachtigall et al. teaches that Danazol, an isoxazol derivative of 17-alpha-ethinyl testosterone, and oral contraceptives, non-steroidal anti-inflammatory, and analgesics are useful in treating endometriosis (See particular page 765 – page 768, col. 1, 4th paragraph).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employing cetrorelix and other agents herein in a method herein to treat endometriosis.

One of ordinary skill in the art would have been motivated to employ cetrorelix and other agents herein in a method herein to treat endometriosis because all the agents herein are known individually to be useful in treating endometriosis. Therefore using the agents herein, in combination or alone, would have been reasonably expected to be useful in a method of treating endometriosis. It is *prima facie* obvious to combine agents each of which is taught by the prior art for the same purpose, in order to form a combination composition to be used for the very same purpose. *In re Kerhkoven* 205, USPQ 1069, 1072 (CCPA 1980). Furthermore, the optimization of result effect parameters (dosage range, dosing frequency and timing) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
July 16, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600